UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 02419
	)	Docket No. 1:13-md-2419-RWZ
This document relates to:	)	
All of the cases against the Box Hill Defendants[2]	)	

BOX HILL DEFENDANTS' FIRST SET OF INTERROGATORIES, REQUESTS FOR PRODUCTION, AND REQUESTS FOR ADMISSION TO ARL BIOPHARMA, INC.

Come the Defendants, Box Hill Surgery Center, LLC, Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., LLC (collectively "Box Hill Defendants"), and submit the following Interrogatories, Requests for Production, and Requests for Admission to ARL BioPharma, Inc., pursuant to Rules 26, 33, 34 and 36 of the Federal Rules of Civil Procedure and Local Rules 33.1, 34.1 and 36.1.

Each of the following Interrogatories shall be answered under oath, in writing, separately, to the fullest possible detail, and in accordance with the definitions and instructions set forth below. The answers shall be signed by the person making them, and a copy of the answers, together with objections, if any, shall be served within 30 days after the service date of these Interrogatories.

You are under a duty to seasonably supplement your responses with respect to any requests directly addressed to the identity and location of persons having knowledge of discoverable matters. You are under a duty to amend a prior response if you obtain information

[2] This pleading applies to the following cases: Handy v. Box Hill Surgery Center, LLC, et al. No: 1:14-cv-14019-RWZ; Armetta v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14022-RWZ; Torbeck v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14023-RWZ; Kashi v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14026-RWZ; Bowman v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14028-RWZ; Dreisch v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14029-RWZ; Davis v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14033-RWZ; Farthing v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14036-RWZ

on the basis of which you know that the response was incorrect when made, or that the response, though correctly made, is no longer true, and the circumstances are such that a failure to amend the response is, in substance, a knowing concealment.

Regarding the following Requests for Admission, Rule 36 of the Federal Rules of Civil Procedure sets forth the following instructions:

a. The grounds for objecting to a request must be stated.

b. A denial must fairly respond to the substance of the requested admission.

c. In the event a portion of the requested admission is true, the party must specify so much of the requested admission that is true, and then qualify or deny the remainder.

d. The answering party may assert lack of knowledge or information as a reason for failing to admit or deny only if the party states that it has made reasonable inquiry and that the information it knows or can readily obtain is insufficient to enable it to admit or deny.

e. A party must not object solely on the ground that the request presents a genuine issue for trial.

INSTRUCTIONS AND DEFINITIONS

I. INSTRUCTIONS

A. If you object to any of the following requests, please respond to as much of the request as to which you have no objection.

B. Your response must include your answers to the Interrogatories and may include objections and assertions of privilege as required under these rules.

C. If you withhold information pursuant to a claim of privilege, please state:

1. that information or material responsive to the request has been withheld;

2. the request to which the withheld material or information relates; and

3. the privilege or privileges asserted.

D. You are under a duty to supplement the following responses if you learn that they were incomplete or incorrect when made or, although complete and correct when made, are no longer complete and correct:

1. to the extent that the written discovery seeks the identification of persons with knowledge of relevant facts, trial witnesses or expert witnesses; and

2. to the extent that the written discovery seeks other information, unless additional or corrective information has been made known in writing, on the record at a deposition, or through other discovery responses.

E. An amended or supplemental response to these requests must be made reasonably promptly after you discover the necessity for such response, but in no event less than 120 days prior to trial.

F. In the event any question cannot be fully answered after the exercise of reasonable diligence, please furnish as complete an answer as you can and explain in detail the reasons why you cannot give a full answer.

G. Unless otherwise noted, the timeframe for these discovery requests is January 1, 2010 to December 31, 2012.

II. DEFINITIONS

A. As used herein, "ARL," "you," and "your" refer to ARL BioPharma, Inc. d/b/a/ Analytical Research Laboratories, an Oklahoma corporation with a principal place of business located at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma, and each of its present and former owners, managers, agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his/her/their behalf.

B. As used herein, the term "Lawsuit" refers to all lawsuits involved in *In re New England Compounding Pharmacy, Inc. Products Liability Litigation,* MDL No. 2419, Dkt. No. 1:13-md-2419, pending in the United States District Court for the District of Massachusetts.

C. As used herein, "Plaintiff" and "Plaintiffs" refer to the Plaintiffs in this Lawsuit who have pending and active cases, as well as their agents, heirs, personal representatives, and assigns, and each person acting or purporting to act on his/her/their behalf.

D. As used herein, "NECC" refers to New England Compounding Pharmacy, Inc., d/b/a/ New England Compounding Center, with its principal place of business located in Framingham, Massachusetts, and each of its present and former owners, manages, agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his/her/their behalf.

E. As used herein, "Ameridose" refers to Ameridose, LLC, a Massachusetts limited liability company with its principal offices located at 205 Flanders Road, Westborough,

Massachusetts, and each of its present and former owners, managers, agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his/her/their behalf.

F. As used herein, the term "NECC facility" refers to the facility located on Waverly Street, Framingham, MA 01702, where compounding of the pharmaceuticals at issue in this Lawsuit occurred.

G. As used herein, the term "MPA" means methylprednisolone acetate.

H. As used herein, the term "USP" refers to United States Pharmacopeia, a nonprofit private group that develops standards of drug quality. "USP" followed by a chapter or section number refers to the indicated chapter or section of USP standards and/or tests.

I. As used herein, the terms "NECC product" and "NECC products" refer to any compounded drug(s) that NECC or Ameridose provided to you for testing in 2012, including but not limited to compounded medications or pharmaceuticals.

J. As used herein, "NECC cleanrooms" refers to the cleanrooms at the NECC facility.

K. As used herein, the term "communication" includes, without limitation, every manner or means of statement, utterance, notation, disclaimer, transfer, or exchange of information of any nature whatsoever, by or to whomever, whether oral, written, or face-to-face, by telephone, U.S. mail or other delivery service, facsimile, personal delivery, electronic mail, computer, or otherwise, specifically including, without limitation, correspondence, conversations, dialogue, discussions, interviews, consultations, agreements, and other understandings.

L. As used herein, the term "document" means any writing and other tangible thing in the custody, possession or control, or which was, but is no longer in the possession, custody or control, of the answering party or known to the answering party – whether printed, recorded, reproduced by any process, or written or produced by hand, and whether or not claimed to be privileged or exempt from production for any reason – including, but not limited to, letters, reports, agreements, all official and personal communication, correspondence, telegraphs, memoranda, summaries, computer files or other electronic media, e-mails, records of personal conversations, formal or informal notes, diaries, forecasts, photographs, tape recordings, charts, plans, drawings, minutes or recordings of conferences, expressions or statements of policy, lists of persons attending meetings or conferences, summaries of interviews, reports and/or summaries of investigations, opinions or reports of records, and drafts of any documents, including original or preliminary drafts and subsequently revised versions. Any comment or notation appearing on any document, and not part of the original text, is to be considered a separate "document." Requests for a "document" specifically includes electronic or magnetic data.

M. As used in this document, the terms "identification" "identify," or "identity," when used in reference.

a. to a person, means to state his or her full name and present or last known residential address and phone number;
b. to a firm, company, business, trust, corporation, partnership, association, governmental agency, governmental unit, or other organization and/or entity, means to state its full name and present or last known business address and phone number;

c. to a statement and/or admission, means to identify who made it, who took or recorded it, and all others, if any, present during the making thereof; to state when, where and how it was taken or recorded, and to identify who has present possession custody or control thereof and/or who last had possession, custody, or control thereof;

d. to tangible things, recordings, photographs, videotapes, motion pictures, x-rays, and/or radiographic films means to give a reasonably detailed description thereof, including, if applicable, when, where, and how made; to identify who made it, and who has present possession, custody or control thereof, and/or who last had possession, custody or control thereof; and

e. to any documents, writings, and/or recordings means to set forth where the document exists, the date of authorship, the name of the author(s), a reasonably detailed description of its contents and all attachments to the original document, and the number of pages in the document and all attachments to the original document, and who has present possession, custody or control thereof, and/or who last had possession, custody or control thereof.

N. As used herein, the terms "concerning," "refer or relate," or "referring or relating" mean, without limitation, referring to, relating to, having any relationship to, pertaining to, evidencing or constituting evidence of, originated by, representing, memorializing, summarizing, describing, discussing, analyzing, evaluating, directly or indirectly, or in whole or in part, the subject matter of the particular request.

O. As used in herein, the term "person" includes any individual, natural person, partnership, association, organization, corporation, company, joint venture, firm, proprietorship, trust, estate, agency, board, authority, commission, or other legal or business entity of any kind.

P. The singular includes the plural number and vice versa. The masculine includes the feminine and neutral gender. The past tense includes the present tense where the clear meaning is not distorted by change of tense.

Q. The term "any" should be construed to include the word "all," and "all" should be construed to include "any."

R. The terms "and," "or," and "and/or" should be construed either disjunctively or conjunctively so as to bring within the scope of these Interrogatories and Requests any information that might otherwise be construed as outside their scope.

REQUEST FOR ADMISSION

REQUEST FOR ADMISSION NO. 1: Admit that you were hired by NECC to test NECC products, including but not limited to MPA.

RESPONSE:

REQUEST FOR ADMISSION NO. 2: Admit that you were hired by Ameridose to test NECC products, including but not limited to MPA.

RESPONSE:

REQUEST FOR ADMISSION NO. 3: Admit that you tested NECC products, including but not limited to MPA, in 2012.

RESPONSE:

REQUEST FOR ADMISSION NO. 4: Admit that you performed sterility testing on NECC products, including but not limited to MPA, in 2012.

RESPONSE:

REQUEST FOR ADMISSION NO. 5: Admit that you performed endotoxin testing on NECC products, including but not limited to MPA, in 2012.

RESPONSE:

REQUEST FOR ADMISSION NO. 6: Admit that you performed fungal testing on NECC products, including but not limited to MPA, in 2012.

RESPONSE:

REQUEST FOR ADMISSION NO. 7: Admit that you owed a duty to exercise reasonable care when testing NECC products.

RESPONSE:

REQUEST FOR ADMISSION NO. 8: Admit that you tested NECC products to determine whether such products were contaminated.

RESPONSE:

REQUEST FOR ADMISSION NO. 9: Admit that you did not discover contamination in any lots of MPA tested in 2012 from NECC or Ameridose prior to the meningitis outbreak at issue.

RESPONSE:

REQUEST FOR ADMISSION NO. 10: Admit that ARL's CEO is Thomas Kupeic, PhD.

RESPONSE:

REQUST FOR ADMISSION NO. 11: Admit that in 2007, Thomas Kupeic, co-authored an article entitled "Quality Control Analytical Methods: The Quality of Sterility Testing," which was published in the International Journal of Pharmaceutical Compounding.[3]

RESPONSE:

REQUEST FOR ADMISSION NO. 12: Admit that the article referenced in Request for Admission No. 11 states, in part, on Page 4:

> "Care must be taken during the compounding process to ensure that the preparation being made is of the highest quality, and microbiology testing is no exception. On a daily basis, quality-control laboratories are on the front line of testing newly formed preparations. With each new drug tested, there is a great responsibility that everything possible is done to ensure that the test result reported is accurate and reliable."

RESPONSE:

REQUEST FOR ADMISSION NO. 13: In 2012, ARL certified NECC MPA lots 052122012@68, 06292012@26, and 08102012@51 ("Contaminated Lots") as sterile.

RESPONSE:

REQUEST FOR ADMISSION NO. 14: ARL did not report contamination in any lots of MPA tested in 2012 from NECC or Ameridose to NECC or any other party.

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[3] McGuire, Jason & Kupiec, Thomas C. Quality Control Analytical Methods: The Quality of Sterility Testing, Int'l J. Pharm. Compl, 2007, Jan-Feb: 11(1), 52, 55 Attached as Exhibit ____.

RESPONSE:

REQUEST FOR ADMISSION NO. 15: Admit that had a customer asked for the sterility testing results for any of the Contaminated Lots, he or she would have received a report from ARL indicating the product was sterile.

RESPONSE:

REQUEST FOR ADMISSION NO. 16: Admit that samples of MPA that NECC sent to ARL for testing were of inadequate size or volume to comply with USP 71.

RESPONSE:

REQUEST FOR ADMISSION NO. 17: Admit that ARL did not notify NECC when NECC sent samples of MPA for testing that were of inadequate size or volume to comply with USP 71.

RESPONSE:

REQUEST FOR ADMISSION NO. 18: ARL did not notify any other part or regulatory agency when NECC sent samples of MPA for testing that were of inadequate size or volume to comply with USP 71.

RESPONSE:

INTERROGATORIES

INTERROGATORY NO. 1: Identify every person providing information used in answering these interrogatories.

ANSWER:

INTERROGATORY NO. 2: Identify by name and job title all of your officers, agents, employees, representatives, and contractors who provided any testing services on NECC products, including but not limited to MPA, in 2012.

ANSWER:

INTERROGATORY NO. 3: Identify each client for whom you provided testing services on MPA in 2011 and 2012.

ANSWER:

INTERROGATORY NO. 4: Identify and describe all testing services you performed on NECC products in 2012.

ANSWER:

INTERROGATORY NO. 5: Identify all policies, procedures, guidelines, standards and practices relating to sterility testing you performed on NECC products in 2012.

ANSWER:

INTERROGATORY NO. 6: Identify all policies, procedures, guidelines, standards and practices relating to fungal testing you performed on NECC products in 2012.

ANSWER:

INTERROGATORY NO. 7: Identify all policies, procedures, guidelines, standards and practices relating to endotoxin testing you performed on NECC products in 2012.

ANSWER:

INTERROGATORY NO. 8: Identify all policies, procedures, guidelines, standards and practices relating to potency testing you performed on NECC products in 2012.

ANSWER:

INTERROGATORY NO. 9: Please describe all measures you took to comply with USP 71 when performing sterility testing on MPA from NECC or Ameridose in 2012.

ANSWER:

INTERROGATORY NO. 10: Describe all of your processes, procedures, and protocols related to ensuring that a customer provides the proper amount of sample material for sterility testing.

ANSWER:

INTERROGATORY NO. 11: Describe all measures you took to determine whether NECC or Ameridose submitted a sufficient amount of sample material for sterility testing of MPA in 2012.

ANSWER:

INTERROGATORY NO. 12: Describe all measures you took relating to testing MPA from NECC or Ameridose for fungal microorganisms in 2012.

ANSWER:

INTERROGATORY NO. 13: Describe all measures you took relating to endotoxin testing on MPA from NECC or Ameridose in 2012.

ANSWER:

INTERROGATORY NO. 14: Describe all investigations you undertook into any testing failures related to any NECC product.

ANSWER:

INTERROGATORY NO. 15: Identify and describe all audits of the testing services you provided to NECC or Ameridose to ensure the accuracy of such testing.

ANSWER:

INTERROGATORY NO. 16: Identify and describe (1) when ARL began providing testing services to New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC") and Ameridose, LLC ("Ameridose"); (2) whether there were any breaks in the period of time that ARL provided testing services (and, if so, when and why); (3) the scope of ARL's work (*e.g.*, to test all medications; to test just certain medications; to only provide certain testing services; etc.); (4) the frequency with which ARL provided those services (*e.g.*, once monthly; once weekly; daily, etc.); and (5) the nature of the services (*i.e.*, what specific testing services ARL provided).

ANSWER:

INTERROGATORY NO. 17: Identify by name and job title all of your officers, agents, employees, representatives, and contractors who acted as an account manager for NECC or were otherwise designated to NECC's account.

ANSWER:

INTERROGATORY NO. 18: Describe in detail ARL's procedures for testing NECC's MPA that ARL received for lot numbers 052122012@68, 06292012@26, and 08102012@51 ("Contaminated Lots"), including:

a. When each lot was tested;
b. All measures ARL took to comply with USP 71 when performing sterility testing;
c. When ARL certified each lot as sterile and free of fungal contamination; and
d. Whether ARL kept an inventory of the samples it received for testing.

ANSWER:

INTERROGATORY NO. 19: Identify the total size of each lot of NECC's MPA that ARL has tested since January 1, 2010.

ANSWER:

INTERROGATORY NO. 20: Identify every instance in which NECC submitted samples of medications for testing that were inadequate for compliance with USP standards, including but not limited to an insufficient number of samples or insufficient sample volume.

ANSWER:

INTERROGATORY NO. 21: For each instance identified in Interrogatory Number 12, identify any and all communications between ARL and NECC regarding the insufficient samples and whether ARL requested additional samples.

ANSWER:

INTERROGATORY NO. 22: Describe in detail "Sterility Testing MBI-144," ARL's "internal method" that ARL advertised on its website in 2012, a printout of which is attached as Exhibit B. Include any way in which the Sterility Testing MBI-144 differed from USP 71-compliant testing in 2012.

ANSWER:

INTERROGATORY NO. 23: Identify the number of times, the dates, and medications on which ARL used "Sterility Testing MBI-144" for NECC products.

ANSWER:

INTERROGATORY NO. 24: Identify each communication you had with NECC notifying them of any problems or concerns with sterility testing either because a sample did not pass sterility testing, was inconclusive, or was insufficient because the sample size was inadequate for any NECC MPA testing, but especially related to lot numbers 052122012@68, 06292012@26, and08102012@51.

ANSWER:

REQUESTS FOR PRODUCTION

REQUEST FOR PRODUCTION NO. 1: The complete customer file you maintain for NECC.

RESPONSE:

REQUEST FOR PRODUCTION NO. 2: The complete customer file you maintain for Ameridose.

RESPONSE:

REQUEST FOR PRODUCTION NO. 3: All proposals, contracts and any other document containing or reflecting the terms and conditions pursuant to which you provided, or proposed providing, testing services for NECC and Ameridose.

RESPONSE:

REQUEST FOR PRODUCTION NO. 4: All marketing materials you ever provided to NECC or Ameridose.

RESPONSE:

REQUEST FOR PRODUCTION NO. 5: All correspondence between you and NECC referring or relating to any testing done on NECC products, including but not limited to MPA, in 2011 and 2012.

RESPONSE:

REQUEST FOR PRODUCTION NO. 6: All correspondence between you and NECC referring or relating to testing methods or procedures you followed when testing NECC products, including but not limited to MPA, in 2012.

RESPONSE:

REQUEST FOR PRODUCTION NO. 7: All correspondence between you and NECC referring or relating to the amount of sample material(s) provided to you by NECC or Ameridose in 2012.

RESPONSE:

REQUEST FOR PRODUCTION NO. 8: All documents referring or relating to sterility testing of NECC products, including but not limited to MPA, in 2012.

RESPONSE:

REQUEST FOR PRODUCTION NO. 9: All documents referring or relating to endotoxin testing of NECC products, including but not limited to MPA, in 2012.

RESPONSE:

REQUEST FOR PRODUCTION NO. 10: All documents referring or relating to fungal testing on NECC products, including but not limited to MPA, in 2012.

RESPONSE:

REQUEST FOR PRODUCTION NO. 11: All documents referring or relating to potency testing on NECC products, including but not limited to MPA, in 2012.

RESPONSE:

REQUEST FOR PRODUCTION NO. 12: All policies, procedures, guidelines, and standards relating to the testing of any NECC product, including but not limited to MPA.

RESPONSE:

REQUEST FOR PRODUCTION NO. 13: All documents referring or relating to audits or other measures you took to ensure the accuracy of testing services you provided to NECC or Ameridose from 2010 to 2012.

RESPONSE:

REQUEST FOR PRODUCTION NO. 14: All documents referring or relating to promises, representations, or warranties made to NECC or Ameridose.

RESPONSE:

REQUEST FOR PRODUCTION NO. 15: All organizational charts for your company that applied during any year in which you performed testing services for NECC or Ameridose.

RESPONSE:

REQUEST FOR PRODUCTION NO. 16: Every page of the http://arlok.com/ website as it existed at any point in 2011 or 2012. If such documents are no longer available, produce documents reflecting the current content of your site.

RESPONSE:

REQUEST FOR PRODUCTION NO. 17: All documents and correspondence exchanged with any member of the PSC relating to NECC or Ameridose or the testing services provided to either.

RESPONSE:

REQUEST FOR PRODUCTION NO. 18: Produce all documents or correspondence with any party referring or relating to NECC or Ameridose submitting an insufficient amount of sample material(s) for sterility or fungal testing.

RESPONSE:

REQUEST FOR PRODUCTION NO. 19: Produce all documents or correspondence with any party referring or relating to NECC or Ameridose products that failed sterility or fungal testing at any time.

RESPONSE:

REQUEST FOR PRODUCTION NO. 20: Produce all correspondence between ARL and NECC about the Contaminated Lots, including but not limited to, communications after the meningitis outbreak.

RESPONSE:

REQUEST FOR PRODUCTION NO. 21: Produce every document request from the PSC and every response given.

RESPONSE:

REQUEST FOR PRODUCTION NO. 22: Produce each and every document produced during mediation.

RESPONSE:

REQUEST FOR PRODUCTION NO. 23: Produce any document or communication with or about Box Hill Surgery Center or the Box Hill Defendants.

RESPONSE:

CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing Interrogatories, Requests for Production of Documents, and Requests for Admission has been served on the below listed counsel for ARL Bio Pharma, Inc., on July 30, 2015 via U.S. Mail, postage pre-paid. Thereafter, a copy was filed on the Court's CM/ECF system to ensure that all interested parties can access it.

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Counsel for ARL Bio Pharma, Inc.

/s/ Gregory K. Kirby
Gregory K. Kirby